Will the Internet of Things Transform Healthcare?

*Nicolas P. Terry**

ABSTRACT

Emerging technologies like health apps on mobile computing platforms and wearable devices are believed to have the potential to improve individual and population health. Increasingly, however, attention should extend to a far larger cohort of connected devices known as the Internet of Things (IoT), an environment in which devices communicate with each other, health apps, and wearables. The resulting Internet of Health Things promises to do things conventional health providers either cannot do or do them faster and cheaper. First, services are "always on," providing twenty-four/seven monitoring of the patient or pre-patient. Second, the multiple sensors contained in smartphones or second-generation wearables like the Apple Watch are professional grade. Third, our smartphones and wearables are highly context aware, with knowledge of place, environmental factors, and, increasingly, other people and things around us. Fourth, they are smart and capable of learning, often leveraging sophisticated, cloud-based analytics. However, the Internet of Health Things (IoHT) is, at least in comparison to conventional healthcare, unregulated or, at best, under regulated. This Article identifies and analyzes three areas of concern: (1) effectiveness and quality, (2) data protection (including pre-patient expectations), and (3) device safety and quality. The Article concludes by examining ways in which the IoHT can improve both traditional healthcare and create new, disruptive approaches to technologically mediated care.

* Hall Render Professor of Law, Executive Director, Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law. Email: npterry@iupui.edu. I thank Professor Miriam Murphy who helped immeasurably with research and Kelci Dye, Indiana University Robert H. McKinney School of Law JD candidate, for her diligent editing.

TABLE OF CONTENTS

I. INTRODUCTION 328
II. DISRUPTION IN HEALTHCARE SPACE 330
III. EFFECTIVENESS WRIT LARGE 334
IV. DATA PROTECTION 337
A. App Store Rules 340
B. Section 5(a) of the Federal Trade Commission Act 340
V. PRODUCT QUALITY AND SAFETY 342
VI. REVISITING THE IoHT VALUE PROPOSITION 346
VII. CONCLUSION 350

I. INTRODUCTION

It has taken less than a decade for smartphones, wearable devices, and mobile health apps (personalized health technologies) to transform the image of healthcare from something provided in centralized institutional settings to something far more convenient and both more personal and more personalized. Suppose, however, that the universe of connected devices stretched far beyond iPhones and FitBits to include Internet-connected appliances, transportation, buildings, and environmental sensors. This Article considers the potential for this Internet of Things (IoT), what the Federal Trade Commission (FTC) describes as "an interconnected environment where all manner of objects have a digital presence and the ability to communicate with other objects and people,"[1] to transform or even disrupt healthcare.

The IoT has the potential to connect apps and wearables to our infrastructure, whether healthcare specific (such as clinics and hospitals) or general (such as homes, offices, or transport).[2] This interconnectivity should enable mobile medical apps and wearables to be more aware of their user's environment and even make changes to that environment to improve the user's health. The IoT may be seen merely as an accelerant increasing the number of healthcare-relevant

1. FED. TRADE COMM'N STAFF REPORT, INTERNET OF THINGS: PRIVACY & SECURITY IN A CONNECTED WORLD 17 (2015) [hereinafter INTERNET OF THINGS], https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf [https://perma.cc/FP6Y-L6K3].

2. David H. Roman & Kyle D. Conlee, *The Digital Revolution Comes to US Healthcare*, 5 INTERNET OF THINGS 1, 15 (June 29, 2015), http://www.scbio.org/resources/Documents/Internet%20of%20Things%20-%20Volume%205%20%20The%20Digital%20Revolution%20comes%20to%20US%20HC%20-%20Jun%2029,%202015%5B1%5D.pdf [https://perma.cc/FB9X-9FYC].

networked devices. However, the combination of personal health technologies and the IoT suggests a powerful Internet of Health Things (IoHT) that features expanded abilities to exchange useful data, improvements in context awareness, and the ability to initiate actions based on data that are collected and analyzed.

Current healthcare policy is focused on increased access, eventual universality,[3] cost control, and the maintenance or increase of quality standards. Those pillars, therefore, continue to reflect the classic "iron triangle" of access versus cost versus quality.[4] Those pillars, however, tend to be qualified by the "triple aim," which is the "simultaneous pursuit of three aims: (1) improving the experience of care, (2) improving the health of populations, and (3) reducing per capita costs of health care."[5] Not surprisingly, contemporary healthcare strategies include investment in the wellness of persons before they become ill (referred to here as "pre-patients"), patients' engagement in their own care, and coordinated care designed to keep local populations healthy and out of the hospital.[6] Some of these strategies were explicitly adopted in the Affordable Care Act[7] by establishing accountable care organizations,[8] research in patient-centered care,[9] and readmission penalties.[10]

In theory, personal health technologies are a good fit for the triple aim.[11] Wellness trackers can engage patients in healthy behaviors, while their diagnostic capabilities could identify medical

---

3. Nicole Huberfeld, *Medicaid at 50: From Exclusion to Expansion to Universality*, HEALTH AFF. BLOG (Nov. 14, 2014), http://healthaffairs.org/blog/2014/11/14/medicaid-at-50-from-exclusion-to-expansion-to-universality/ [https://perma.cc/2L5X-2CBY].

4. WILLIAM L. KISSICK, MEDICINE'S DILEMMAS 2 (1994) (The "iron triangle of health care [], access, quality, and cost containment have equal angles, representing identical priorities, and an expansion of any one angle compromises one or both of the other two.").

5. Donald M. Berwick, Thomas W. Nolan & John Whittington, *The Triple Aim: Care, Health, and Cost*, 27 HEALTH AFF. 759, 759 (2008), http://content.healthaffairs.org/content/27/3/759.full.pdf [https://perma.cc/5MZ4-37Q9].

6. Julia James, *Medicare Hospital Readmissions Reduction Program*, HEALTH AFF. BLOG (Nov. 12, 2013), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=102 [https://perma.cc/4TVW-6T6A].

7. Patient Protection and Affordable Care Act § 2712(a), Pub. L. No. 111–148, 124 Stat. 119 (2010).

8. *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., *Accountable Care Organizations*, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/ACO/ [https://perma.cc/W9BK-CU7T] (last modified Jan. 6, 2015).

9. *See, e.g.*, PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE, http://www.pcori.org/ [https://perma.cc/9VMD-X5TE] (last visited Apr. 3, 2016).

10. James, *supra* note 6.

11. *See generally* Jason Healey, Neal Pollard & Beau Woods, *The Healthcare Internet of Things: Rewards and Risk*, ATLANTIC COUNCIL-INTEL CORP., at 7 (Mar. 18, 2015), http://www.atlanticcouncil.org/publications/reports/the-healthcare-internet-of-things-rewards-and-risks [https://perma.cc/8R9B-G5X9].

problems early enough to allow for less costly intervention. Although conventional healthcare models tend to "push" care to patients, those who are in control of their digital medical selves may be more cost conscious, tending to "pull" resources only when necessary.[12] Additionally, mobile healthcare is nonlinear. Rather than being delivered at centralized, frequently inconvenient locations, mobile technologies are streamed when the patient demands them and are delivered to the patient's location. Further, sophisticated yet inexpensive monitoring of and coaching for chronic conditions may address some of healthcare's fragmentation problems by better coordinating care when patients are handed off between providers.[13]

This Article concerns itself with two questions. First, how likely is it that the IoHT will disrupt or transform conventional models of healthcare, replacing some delivery models rather than merely adding another layer of cost and complexity? Second, what is the role of regulation? Conventional healthcare is highly regulated.[14] In contrast, the IoHT is unregulated or, at best, under regulated, raising questions about IoHT quality, safety, and data protection.

In Part II, this Article summarizes earlier work involving health information technology (HIT), its failure to disrupt conventional healthcare, and how IoHT may result in a different outcome. Parts III, IV, and V balance this initial optimistic picture with concerns that have been raised as to the overall effectiveness, data protection, and safety of early generations of IoHT, particularly apps and wearables. Finally, Part VI reassesses the IoHT value proposition.

II. DISRUPTION IN HEALTHCARE SPACE

A prior article critically examined the financing and implementation of HIT, such as electronic health records (EHR) and

12. John Hagel et al., *A Consumer-Driven Culture of Health*, DELOITTE U. PRESS (Feb. 18, 2015), https://dupress.deloitte.com/dup-us-en/industry/health-care/future-of-us-health-care.html [https://perma.cc/A6PM-8VWK] ("In an open marketplace, consumer demand determines the value of information, products, and services. This is a significant shift from push-based environments where health care players make many business decisions based on the assets they already have in place—there is a concerted effort to squeeze consumer demand into the available assets, even if the fit is not optimal. In the pull-based environment, consumer demand becomes the primary driver of value, and assets that are not effectively responding to the needs of the consumer are much more likely to be shed.").

13. *See generally* Nicolas P. Terry, *Mobile Health: Assessing the Barriers*, 147 CHEST J. 1429, 1429–34 (2015), http://journal.publications.chestnet.org/article.aspx?articleid=2279279 [https://perma.cc/9LKH-C4NK].

14. *See generally* Robert I. Field, *Why Is Health Care Regulation So Complex?* 33 PHARMACY & THERAPEUTICS 607 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2730786/ [https://perma.cc/4SD5-L5NG].

clinical decisions support (CDS) systems.[15] That analysis used the "disruption" work of Clayton Christensen as a framing device.[16] In brief, Christensen argued that incumbents with sustaining technologies will lose out to market entrants with disruptive technologies, even if disruptive technologies initially underperform.[17] Disruption seems to have played out broadly, as technologically enabled market entrants like Apple, Netflix, and Amazon successfully disrupted incumbent businesses dealing in non-digital goods or relying on brick-and-mortar locations.[18]

In contrast, HIT has failed to disrupt healthcare. There are several overlapping explanations. HIT itself suffers from the same types of market failures seen in healthcare generally,[19] from misaligned incentives to public goods issues,[20] which have slowed widespread adoption. Currently, HIT and conventional healthcare do not seem to be a good "fit" because of how healthcare is organized and financed. Also, information technologies typically (and almost by definition) transform industries by changing the way data are collected, shared, and processed.[21] However, healthcare data are themselves fragmented and lack standards that make data "liquid,"[22] which makes it difficult to control and mold them to change the healthcare industry.

Market failure, the first of these explanations, deserves some additional detail. Importantly, third-party reimbursement, healthcare's dominant financing model, "saps motivation for innovation—particularly disruptive innovation—out of the system."[23] The relative failure of the "meaningful use" subsidy program for EHRs[24]

---

15. *See generally* Nicolas P. Terry, *Information Technology's Failure to Disrupt Healthcare*, 13 NEV. L.J. 722, 723 (2013).

16. CLAYTON M. CHRISTENSEN, THE INNOVATOR'S DILEMMA: WHEN NEW TECHNOLOGIES CAUSE GREAT FIRMS TO FAIL, at xv (1997).

17. *Id.*

18. Terry, *supra* note 15, at 726–27.

19. The thing is, "technology scholars" have not posited this—this Author posits it, and not lazily. *See* Energy and Commerce Comm., *Disrupter Series: Health Care Apps*, 114th Cong. (July 13, 2016) [hereinafter *Disrupter Series*], https://energycommerce.house.gov/hearings-and-votes/hearings/disrupter-series-health-care-apps [https://perma.cc/FBU9-584Y].

20. *See generally* Austin Frakt, *Health Care Market Failures (and What Can Be Done About Them)*, INCIDENTAL ECONOMIST (Feb. 17, 2011), http://theincidentaleconomist.com/wordpress/health-care-market-failures-and-what-can-be-done-about-them/ [https://perma.cc/C7L6-CRDG].

21. *See generally* Terry, *supra* note 15, at 749.

22. *Id.*

23. CLAYTON M. CHRISTENSEN ET AL., SEEING WHAT'S NEXT: USING THE THEORIES OF INNOVATION TO PREDICT INDUSTRY CHANGE 197 (2004).

24. *See generally* Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know About the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records*, 34 J. LEGAL MED. 7, 32 (2013).

suggests not only a HIT market failure but also that EHR technologies have consistently underperformed.[25] Finally, there may be stakeholder confusion caused by positive outliers, such as vertically integrated providers like the Veteran's Administration[26] and some large Health Management Organizations (HMOs).[27] Disruption of conventional healthcare was, perhaps, always impossible, but even the path to transforming the existing model of care through technology seems difficult.

Personal health technologies tend to avoid many of the problems associated with HIT, suggesting that they may disrupt some aspects of healthcare.[28] Christensen himself noted that, although disruptive technologies initially tend to underperform, they tend to succeed if they are "typically cheaper, simpler, smaller, and, frequently, more convenient to use" than existing mainstream products.[29] "New-market disruptive innovations . . . occur when characteristics of existing products limit the number of potential consumers or force consumption to take place in inconvenient, centralized settings."[30] The software of personal health technologies—mobile apps—offers alternatives to these inconveniences: they are accessible by anyone with a smart device and can be utilized in any number of locales, not just a physician's office.

And if mobile apps are the software of personal health technologies, "wearables" are the hardware. Wearables include not only well-known technologies like fitness bands and smart watches, but also sophisticated biosensors that are attached directly to or implanted in the human body. Various explanations for the popularity of wearables abound, including the rise in employer-sponsored wellness

25. *See generally* Nicolas P. Terry, *Pit Crews with Computers: Can Health Information Technology Fix Fragmented Care?*, 14 HOUS. J. HEALTH L. & POL'Y 129, 169–70 (2014).

26. *See generally* Jian Gao et al., *Variations in Efficiency and the Relationship to Quality of Care in the Veterans Health System,* 30 HEALTH AFF. 655, 656 (2011), http://content.healthaffairs.org/content/30/4/655.full [https://perma.cc/ZS5S-NSWR].

27. *See generally* Jeff Goldsmith, *An Interview with George Halvorson: The Kaiser Permanente Renaissance, and Health Reform's Unfinished Business*, HEALTH AFF. BLOG (Sept. 30, 2014), http://healthaffairs.org/blog/2014/09/30/an-interview-with-george-halvorson-the-kaiser-permanente-renaissance-and-health-reforms-unfinished-business/ [https://perma.cc/9G47-E3E2].

28. *See generally* Nicolas P. Terry, *supra* note 15.

29. CHRISTENSEN, *supra* note 16, at 232.

30. CHRISTENSEN ET AL., *supra* note 23, at xvii.

programs,[31] the popularity of quantified self-movement,[32] sousveillance,[33] and the gamification of healthcare.[34]

Although health-related wearables themselves are examples of the IoT, the IoT concept goes further to include multiple networks, platforms, and connected devices.[35] According to the FTC, "[t]he IoT explosion is already around us, in the form of wearable computers, smart health trackers, connected smoke detectors and light bulbs, and essentially any other Internet-connected device that is not a mobile phone, tablet, or traditional computer."[36]

In 2015, there were more than 165,000 mobile health apps available for download from Apple and Android app stores.[37] The number in the Apple store had doubled in two years.[38] There has been a similar explosive growth in the wearables market with fitness and wellness "bands," smart watches, and smart patches.[39] As early as 2016

---

31. *See generally Wellness at Work*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/features/workingwellness/ [https://perma.cc/9XXS-TGS6] (last visited Nov. 10, 2016); *see also* FITBIT GROUP HEALTH, https://www.fitbit.com/group-health [https://perma.cc/K5D2-7GLT] (last visited Nov. 10, 2016).

32. *Counting Every Moment*, ECONOMIST (Mar. 3, 2012), http://www.economist.com/node/21548493 [https://perma.cc/QW5T-ZUBE].

33. Jascha Hoffman, *Sousveillance*, N.Y. TIMES (Dec. 10, 2006), https://nyti.ms/2k9I3gT [https://perma.cc/3SE6-4XDA]; *Definition of: Sousveillance*, PCMAG.COM, http://www.pcmag.com/encyclopedia/term/66453/sousveillance [https://perma.cc/4DHQ-NV56] (last visited Apr. 4, 2016).

34. *Gamification*, MASHABLE, http://mashable.com/category/gamification/ [https://perma.cc/345X-MUEX] (last visited Dec. 1, 2016); *see also How Companies Are Using Gamification to Transform Health Care*, BUS. INSIDER (Jan. 18, 2013, 9:04 AM), http://www.businessinsider.com/gamification-in-healthcare-2013-1 [https://perma.cc/PU7A-698W].

35. *See generally* Andrew Meola, *Internet of Things Devices, Applications & Examples*, BUS. INSIDER (Aug. 15, 2016, 3:04 PM), http://www.businessinsider.com/internet-of-things-devices-applications-examples-2016-8 [https://perma.cc/SP6P-VV8T]; Daniel Burrus, *The Internet of Things Is Far Bigger Than Anyone Realizes*, WIRED, https://www.wired.com/insights/2014/11/the-internet-of-things-bigger/ [https://perma.cc/UJM2-F6X4] (last visited Dec. 1, 2016).

36. INTERNET OF THINGS, *supra* note 1, at 1.

37. *Things Are Looking App*, ECONOMIST (Mar. 12, 2016), http://econ.st/1LTcoNq [https://perma.cc/U2FA-24B3].

38. *IMS Health Study: Patient Options Expand as Mobile Health Apps Address Wellness and Chronic Disease Treatment Needs*, BUS. WIRE (Sept. 17, 2015, 8:00 AM), http://www.businesswire.com/news/home/20150917005044/en/IMS-Health-Study-Patient-Options-Expand-Mobile [https://perma.cc/E84C-GVPA].

39. *See generally How Emerging Consumer and Professional Healthcare Trends Are Driving Interest in Wearable Devices*, BUS. INSIDER (Mar. 4, 2015, 3:00 PM), http://www.businessinsider.com/the-wearables-in-the-healthcare-sector-report-how-emerging-consumer-and-professional-healthcare-trends-are-driving-interest-in-wearables-2015-10 [https://perma.cc/6XLR-JC3B]; Eric Wicklund, *Wearables Find Their Sticking Point in Healthcare*, MHEALTH INTELLIGENCE (Mar. 14, 2016), http://mhealthintelligence.com/news/wearables-find-their-sticking-point-in-healthcare [https://perma.cc/WZ8M-82JE]; Ayliffe Brown, *Technology That Is Flexible, Sticky, and Smart = Wearable Patches*, WEARABLE TECHS. (Aug. 17, 2015),

analysts predict that worldwide shipments of wearable devices will exceed $111 million,[40] and the market for wearable technology will reach $70 billion by 2025.[41] The IoT is even larger and growing exponentially: "[in 2015,] 25 billion connected devices, and by 2020, 50 billion."[42] The IoHT market is estimated to reach $117 billion by 2020.[43]

This resulting combination of mobile apps, wearables, and the IoT promises to do things no conventional health providers have been able to do—and to do them faster and cheaper. First, the IoHT is always "on," promising twenty-four seven monitoring of the pre-patient or patient. Second, the multiple sensors contained in smartphones or second-generation wearables, such as the Apple Watch, are professional-grade medical devices suggesting an increase in the quality of the data being collected. Third, the IoHT is highly context aware, with knowledge of place, environmental factors, and, increasingly, other connected people and things nearby.[44] Fourth, the IoHT will be smart and capable of machine learning, often leveraging sophisticated, cloud-based analytics.[45]

III. EFFECTIVENESS WRIT LARGE

Both pre-patient–facing and patient-facing apps and wearables enjoy immense popularity.[46] They also fit the disruption model: they avoid third-party reimbursement by delivering care directly to pre-patients and patients, are convenient, and are generally inexpensive. However, are they truly disruptive technologies that offer effective

---

http://www.wearable-technologies.com/2015/08/technology-that-is-flexible-sticky-and-smart-wearable-patches/ [https://perma.cc/VX5V-TSHB].

40. Willa Plank & Tristan Wyatt, *The Future of the Wearables Market*, WALL ST. J. (Jan. 13, 2016), http://www.wsj.com/articles/the-future-of-the-wearables-market-1452736738 [https://perma.cc/ZL2Y-YWFE].

41. James Hayward, *Sensors Enabling a $70bn Wearable Technology Market by 2025*, IDTECHEX (Sept. 2, 2015), www.idtechex.com/research/articles/sensors-enabling-a-70bn-wearable-technology-market-by-2025-00008344.asp+&cd=3&hl=en&ct=clnk&gl=us&client=safari [https://perma.cc/35GE-96DL].

42. INTERNET OF THINGS, *supra* note 1, at i.

43. TJ McCue, *$117 Billion Market for Internet of Things in Healthcare by 2020*, FORBES (Apr. 22, 2015), http://www.forbes.com/sites/tjmccue/2015/04/22/117-billion-market-for-internet-of-things-in-healthcare-by-2020/#66859d2c2471 [https://perma.cc/Q9BV-VCQE].

44. *See, e.g.*, Kevin Lonergan, *The Autonomous Internet of Things: How the IoT Will Become Context-Aware and Self-Sufficient*, INFO. AGE (Jan. 7, 2016), http://www.information-age.com/autonomous-internet-things-how-iot-will-become-context-aware-and-self-sufficient-123460740 [https://perma.cc/S5WV-XASA].

45. Jimmy Pike, *The Internet of Things and Machine Learning*, FORBES (Mar. 16, 2016), http://www.forbes.com/sites/moorinsights/2016/03/16/the-internet-of-things-and-machine-learning/#34761987483e [https://perma.cc/CP8K-MR8D].

46. *See generally* Gregory Schmidt, *Fitness Trackers Move to Earphones, Socks and Basketballs*, N.Y. TIMES (May 11, 2016), https://nyti.ms/2k9xbzA [https://perma.cc/MF3B-2TTM].

substitutes for conventional healthcare? Or are these merely an upgrade to some existing provider-facing technologies combined with some additive pre-patient or patient-facing services? After all, retail medical clinics, another innovation that promised to improve access and decrease costs,[47] now seem responsible for some *increase* in healthcare costs.[48]

Certainly there are reasons to be skeptical about some of the claims for personal health technologies. First, the cohorts most likely to adopt wearables exhibit both digital and health literacy and generally have good health determinants. Arguably, and notwithstanding the gains made in reducing the numbers of uninsured following passage of the Affordable Care Act (ACA),[49] it is those living in poverty, those with poor health determinants, the uninsured, and the growing ranks of underinsured[50] that the healthcare system must reach.[51] However, a business model for serving this population with digital health services has not yet emerged.[52]

Second, there are suspicions that the promise of mobile medical apps and wearables has been oversold, even that they have failed to solve any tangible problems. For example, one recent study of fitness or wellness apps concluded that "[t]he gap between recording information and changing behavior is substantial" and there was "little evidence . . . that they are bridging that gap."[53]

---

47. *See generally* William M. Sage, *Out of the Box: The Future of Retail Medical Clinics*, 3 HARV. L. & POL'Y REV. ONLINE 1 (2009).

48. J. Scott Ashwood et al., *Retail Clinic Visits for Low-Acuity Conditions Increase Utilization and Spending*, 35 HEALTH AFF. 449 (2016), http://content.healthaffairs.org/content/35/3/449.abstract [https://perma.cc/SLM3-KLFY].

49. *See generally Health Insurance Coverage and the Affordable Care Act*, ASPE (May 5, 2015), https://aspe.hhs.gov/pdf-report/health-insurance-coverage-and-affordable-care-act [https://perma.cc/8H28-LNDK].

50. *See generally 31 Million People Were Underinsured in 2014; Many Skipped Needed Health Care and Depleted Savings to Pay Medical Bills*, COMMONWEALTH FUND (May 20, 2015), http://www.commonwealthfund.org/publications/press-releases/2015/may/underinsurance-brief-release [https://perma.cc/Q25M-VZ84].

51. *See generally* Emily Kontos et al., *Predictors of eHealth Usage: Insights on the Digital Divide from the Health Information National Trends Survey 2012*, 16(7) J. MED. INTERNET RES. (2014), https://www.jmir.org/2014/7/e172/ [https://perma.cc/CNG3-5SKP]; Amy Roeder, *An Unhealthy Digital Divide*, HARV. SCH. PUB. HEALTH (Jan 28, 2014), http://www.hsph.harvard.edu/news/features/unhealthy-digital-divide [https://perma.cc/YQL7-3QAP].

52. Barbara Feder Ostrov, *'Digital Health' Not Just for Well-Heeled Fitness Fiends*, CALIFORNIAHEALTHLINE (June 24, 2016), http://californiahealthline.org/MjAwMjgy [https://perma.cc/GEC2-QN9D].

53. Mitesh S. Patel et al., *Wearable Devices as Facilitators, Not Drivers, of Health Behavior Change*, 313(5) J. AM. MED. ASSOC. 459 (2015), http://jamanetwork.com/journals/jama/article-abstract/2089651 [https://perma.cc/GW3E-DGES].

Third, there is a growing body of evidence that the current generations of mobile apps and wearables do not perform particularly well. For example, fitness trackers are generally quite poor at tracking sleep patterns using only their accelerometers,[54] the "conversational agents" that increasingly operate as interfaces on our devices tend not to be particularly good at responding to healthcare emergencies,[55] and many devices fail to validly measure energy expenditure.[56]

Fourth, it is relatively easy to paint some dystopian scenarios fueled by the IoHT. One hopefully extreme example is a wristband that not only turns down your heat but also gives you an electric shock when your bank balance is low.[57] More seriously, those programming the IoHT will have to confront the well-known "Trolley Problem;"[58] some of the ethical questions posed by that hypothetical, such as to the relative worth of persons when life-threatening or injurious circumstances arise, should be predictable and will have to be answered in the program code.[59] Not quite as dystopian but likely to affect many more persons are questions about the self-quantification of daily activities by using trackers like Fitbit wearables. Arguably, the popularity of such devices has been promoted through gamification. However, there is research suggesting that quantifying heretofore enjoyable life activities undermines intrinsic motivation and makes the activities seem "more like work,"[60] "[r]educing daily experience to a series of boxes checked and numerical goals met coloniz[ing] consumers' leisure time with the

---

54. Rachael Rettner, *Fitness Trackers & Sleep: How Accurate Are They?*, LIVE SCI. (Jan. 20, 2014), https://shar.es/1O6bTo [https://perma.cc/ZAZ3-AVMU].

55. Adam S. Miner et al., *Smartphone-Based Conversational Agents and Responses to Questions About Mental Health, Interpersonal Violence, and Physical Health*, 176(5) J. MED. INTERNET RES. 619, 621 (2016), http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2500043 [https://perma.cc/9M4V-YAAT].

56. Haruka Murakami et al., *Accuracy of Wearable Devices for Estimating Total Energy Expenditure: Comparison with Metabolic Chamber and Doubly Labeled Water Method*, 176(5) J. MED. INTERNET RES. 700, 702 (2016), http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2500062 [https://perma.cc/W7K3-7B2T]; Nelson, Kaminsky, Dickin & Montoye, *Validity of Consumer-Based Physical Activity Monitors for Specific Activity Types*, 48(8) MED. SCI. SPORTS EXERCISE 1619, 1619 (2016), https://www.ncbi.nlm.nih.gov/pubmed/27015387 [https://perma.cc/3D7R-YFTK].

57. Zoe Kleinman, *The UK Firm That Wants to Give Big Spenders a Big Shock*, BBC NEWS (May 19, 2016), http://www.bbc.com/news/technology-36301778 [https://perma.cc/8W5V-XE5C].

58. *See generally* Sarah Bakewell, *Clang Went the Trolley*, N.Y. TIMES (Nov. 22, 2013), http://www.nytimes.com/2013/11/24/books/review/would-you-kill-the-fat-man-and-the-trolley-problem.html [https://perma.cc/KC2B-DWCS].

59. *See also* Patrick Lin, *The Ethics of Autonomous Cars*, ATLANTIC (Oct. 8, 2013), https://www.theatlantic.com/technology/archive/2013/10/the-ethics-of-autonomous-cars/280360/?utm_source=twb [https://perma.cc/ZSR7-EJSF].

60. Jordan Etkin, *The Hidden Cost of Peronal Quantification*, 42 J. CONSUMER RES. 967, 968 (2016), https://academic.oup.com/jcr/article/42/6/967/2358309/The-Hidden-Cost-of-Personal-Quantification [https://perma.cc/Y3KU-AVVH].

same disciplined logic of their working days."[61] These tendencies will likely increase as employers and life insurers create pressure through, for example, wellness plans[62] or insurance premium discounts designed to promote the use of fitness devices.[63] The question may quickly evolve into how and where we can be forced to use trackers[64] and what limitations apply to the use of data they collect.[65]

IV. DATA PROTECTION

According to the CEO of wearable-manufacturer Under Armour,[66] "data is the new oil."[67] As this oil rush gathers speed, there are persistent reports of privacy and security flaws in apps, wearables, and IoHT devices.[68] Many mobile hardware devices have critical security vulnerabilities,[69] and medical apps have been found to have

61. Frank Pasquale, *How Fitness Trackers Make Leisure More Like Work*, ATLANTIC (Mar. 2, 2016), http://www.theatlantic.com/business/archive/2016/03/how-trackers-make-leisure-like-work/471864/?utm_source=twb [https://perma.cc/W9L5-MTD8].

62. *See generally* James A. Martin, *Pros and Cons of Using Fitness Trackers for Employee Wellness*, CIO (Mar. 24, 2014), http://www.cio.com/article/2377723/it-strategy/pros-and-cons-of-using-fitness-trackers-for-employee-wellness.html [https://perma.cc/295Y-HLS5].

63. *See, e.g.*, Christina Farr, *Weighing Privacy Vs. Rewards of Letting Insurers Track Your Fitness*, NPR (Apr. 9, 2015, 7:08 AM), http://www.npr.org/blogs/alltechconsidered/2015/04/09/398416513/weighing-privacy-vs-rewards-of-letting-insurers-track-your-fitness [https://perma.cc/TUK5-SD3A].

64. *See* Suzanne McGee, *How Employers Tracking Your Health Can Cross the Line and Become Big Brother*, GUARDIAN (May 1, 2015), https://www.theguardian.com/lifeandstyle/us-money-blog/2015/may/01/employers-tracking-health-fitbit-apple-watch-big-brother [https://perma.cc/EYF5-EXRA].

65. *See* Jocelyn Samuels, *How HIPAA Applies to Certain Workplace Wellness Programs*, U.S. DEP'T. HEALTH & HUM. SERV. (Mar. 14, 2016), http://www.hhs.gov/blog/2016/03/14/how-hipaa-applies-certain-workplace-wellness-programs.html [https://perma.cc/TC8L-MY6X]. *See generally* Patience Haggin, *As Wearables in Workplace Spread, So Do Legal Concerns*, WALL ST. J. (Mar. 13, 2016), https://www.wsj.com/articles/as-wearables-in-workplace-spread-so-do-legal-concerns-1457921550? [https://perma.cc/E7S5-Q55A].

66. *See generally* David Pierce, *How Under Armour Plans to Turn Your Clothes into Gadgets*, WIRED (Jan. 5, 2016), https://www.wired.com/2016/01/under-armour-healthbox/ [https://perma.cc/3TLK-UTDG].

67. Christopher Heine, *Under Armour's CEO Just Hinted at How His Company Can Grow to $7 Billion by 2018*, ADWEEK (Mar. 14, 2016), http://adweek.it/1Uu1T4y [https://perma.cc/F7LC-DHWE].

68. *See generally* Shaun Nichols, *It's 2016 and Now Your Internet-Connected Bathroom Scales Can Be Hacked*, REGISTER (Apr. 29, 2016), http://www.theregister.co.uk/2016/04/29/fitbit_aria_scales_security_flaw/ [https://perma.cc/K2GK-LPD9].

69. Daniel R. Thomas et al., *Security Metrics for the Android Ecosystem*, ACM (Oct. 12, 2015), https://www.cl.cam.ac.uk/~drt24/papers/spsm-scoring.pdf [https://perma.cc/Y895-PSHT]; *see e.g.*, Zack Whittaker, *Widely-Used Patient Care App Found to Include Hidden 'Backdoor' Access*, ZDNET (May 27, 2016), http://www.zdnet.com/article/widely-used-clinical-service-found-to-include-hidden-backdoor-account/ [https://perma.cc/K7E2-BT2Y].

only low levels of encryption or adequate data privacy policies,[70] while many fitness devices emit persistent, unique Bluetooth identifiers that could permit the tracking of users.[71] Numerous reports of IoT devices demonstrate the lack of even basic security[72] and have published proof-of-concept "hacks" of connected devices,[73] including medical devices.[74] Meanwhile, developers who commit to user "privacy by design" find the process difficult and sometimes at odds with technical innovation.[75]

The question whether developers of mobile medical apps or data custodians collecting health data from IoT devices are covered by the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules is difficult because the HIPAA rules apply to healthcare providers, not simply to all medical information.[76] They do

---

70. Kit Huckvale et al., *Unaddressed Privacy Risks in Accredited Health and Wellness Apps: A Cross-Sectional Systematic Assessment*, 13 BMC MED. 214 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4582624/ [https://perma.cc/79EK-4L3G]; Sarah R. Blenner et al., *Privacy Policies of Android Diabetes Apps and Sharing of Health Information*, 315(10) J. MED. INTERNET RES. 1051 (2016), http://jamanetwork.com/journals/jama/fullarticle/2499265 [https://perma.cc/XX6D-L7SM].

71. Andrew Hilts, Christopher Parsons & Jeffrey Knockel, *Every Step You Fake: A Comparative Analysis of Fitness Tracker Privacy and Security*, OPEN EFFECT, at 22 (Apr. 18, 2016), https://openeffect.ca/reports/Every_Step_You_Fake.pdf [https://perma.cc/7Y95-VAZS].

72. *See, e.g.*, *I Stayed in a Hotel with Android Lightswitches and It Was Just as Bad as You'd Imagine*, DREAM WIDTH (Mar. 11, 2016, 1:36 PM), http://mjg59.dreamwidth.org/40505.html [https://perma.cc/2FPP-79LK]; Aamna Mohdin, *Are You Being Watched Right Now? There's a Creepy Search Engine for Unsecured Webcams*, QUARTZ (Jan. 25, 2016), https://qz.com/602218 [https://perma.cc/M49X-KXKJ]

73. *See, e.g.*, Andy Greenberg, *Hackers Remotely Kill a Jeep On The Highway—with Me in It*, WIRED (July 21, 2015), https://www.wired.com/2015/07/hackers-remotely-kill-jeep-highway/ [https://perma.cc/SD3A-MAYV]; David Shepardson, *FBI Warns Automakers, Owners About Vehicle Hacking Risks*, REUTERS (Mar. 17, 2016), http://www.reuters.com/article/us-fbi-autos-cyber-idUSKCN0WK0BB [https://perma.cc/BU9F-2KUS]; Andy Greenberg, *Radio Attack Lets Hackers Steal 24 Different Car Models*, WIRED (Mar. 21, 2016), https://www.wired.com/2016/03/study-finds-24-car-models-open-unlocking-ignition-hack/ [https://perma.cc/8H2R-CHE5].

74. Dan Goodin, *Insulin Pump Hack Delivers Fatal Dosage Over the Air*, REGISTER (Oct. 27, 2011), http://www.theregister.co.uk/2011/10/27/fatal_insulin_pump_attack/ [https://perma.cc/L2E8-GDHN]; Alexandra Ossola, *Hacked Medical Devices May Be the Biggest Cyber Security Threat in 2016*, POPULAR SCI. (Nov. 23, 2015), http://www.popsci.com/hackers-could-soon-hold-your-life-ransom-by-hijacking-your-medical-devices [https://perma.cc/T9GZ-BXTA]; Harriet Taylor, *How the 'Internet of Things' Could Be Fatal*, CNBC (Mar. 4, 2016), http://www.cnbc.com/2016/03/04/how-the-internet-of-things-could-be-fatal.html [https://perma.cc/4T3J-ZP2A]; Darlene Storm, *1,418 Remotely Exploitable Flaws Found in Automated Medical Supply System*, COMPUTERWORLD (Mar. 30, 2016), http://www.computerworld.com/article/3049361/security/1-418-remotely-exploitable-flaws-found-in-automated-medical-supply-system.html [https://perma.cc/WXG8-N4DH]; Matt Egan, *Pacemaker Hacking Claims 'Absolutely Untrue': St. Jude*, CNN MONEY (Aug. 25, 2016), http://cnnmon.ie/2blw7Ja [https://perma.cc/E4S3-5CH5].

75. *See* Julia Love, *Apple 'Privacy Czars' Grapple with Internal Conflicts Over User Data*, REUTERS (Mar. 21. 2016), http://reut.rs/1UwleU2 [https://perma.cc/A46B-MMNG].

76. *See generally* 45 C.F.R. §§ 160, 162, 164 (2016).

apply to most providers or insurers of conventional healthcare ("covered entities")[77] and to the "business associates"[78] of those parties. As a result, covered entities or their developers who create apps for, say, patient monitoring, disease management, or integration with their electronic health records, typically will be covered by the HIPAA rules.[79] However, most mobile health hardware and software developers will not be healthcare providers or their contractors and, as a result, will not be HIPAA "covered entities" or "business associates."[80]

Overall, the present regulatory status of mobile health apps is sufficiently complicated that the Health and Human Services Office for Civil Rights (HHS-OCR), the Federal Trade Commission (FTC), and the Food and Drug Administration (FDA) jointly developed an interactive tool in an attempt to guide application, or app, developers through the regulatory confusion.[81] However, our contemporary data protection tools likely are not up to the task. Healthcare data will increasingly be created outside of the HIPAA protected zone.[82] Ironically, a Congress that has failed to pass comprehensive privacy and security legislation to deal with this problem seems intent on blaming a relatively powerless Department of Health & Human Services (HHS) for the resulting legal indeterminacy.[83]

The dichotomy between the highly regulated HIPAA zone and the lightly regulated external zone is a function of the sectoral approach to data protection in the United States.[84] Furthermore, what data protection we have is premised on the institutional collection of data. Increasingly, however, the default custodian is the data subject using a personal device. The common law of confidence and some state health

---

77. *See* 45 C.F.R. § 160.102.

78. *Id.*; *see generally* 45 C.F.R. §§ 164.502(e), 164.504(e), 164.532(d) & (e).

79. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., HEALTH APP USE SCENARIOS & HIPAA (2016), http://src.bna.com/djt [https://perma.cc/UY4H-UT9T].

80. *See generally Covered Entities and Business Associates*, U.S. DEP'T HEALTH & HUMAN SERVS., http://www.hhs.gov/hipaa/for-professionals/covered-entities/ [https://perma.cc/76DZ-9N3K] (last visited Dec. 1, 2016).

81. *Mobile Health Apps Interactive Tool*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool [https://perma.cc/EN7F-9B9V] (last visited Dec. 1, 2016).

82. Nicolas P. Terry, *Big Data Proxies and Health Privacy Exceptionalism*, 24 HEALTH MATRIX 65, 82–84 (2014).

83. *See* Congress of the U.S., Opinion Letter to Secretary Burwell, U.S. Dep't of Health & Human Services (Mar. 9, 2016), https://marino.house.gov/sites/marino.house.gov/files/documents/03.09.16%20Marino%20DeFazio%20Ltr%20to%20HHS%20on%20HIPAA%20for%20Mobile%20App%20Developers.pdf [https://perma.cc/N55R-QG9D].

84. Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Healthcare Data Protection*, 17 YALE J. HEALTH POL'Y L. & ETHICS (forthcoming 2017), https://papers.ssrn.com/sol3/papers2.cfm?abstract_id=2774471 [https://perma.cc/PL2E-X688].

privacy laws may have limited application, but, currently, most data protection implicating apps, wearables, and IoHT devices will be provided by app store rules and the growing jurisprudence of the FTC.[85]

A. App Store Rules

As to the former, only Apple has a rigorous set of rules.[86] App developers are required to publish a privacy policy and must respect basic privacy principles, such as transparency and context limitations.[87] In addition, Apple's app store has specific rules that govern how apps should treat customer data.[88] For example, the app store rules expressly prohibit health-related apps from using collected data for advertising or other use-based data mining purposes.[89]

B. Section 5(a) of the Federal Trade Commission Act

The FTC's general powers are found in Section 5(a) of the Federal Trade Commission Act (FTCA), which prohibits "unfair or deceptive acts or practices in or affecting commerce[.]"[90] Not surprisingly, the FTC has used the deceptiveness prong of Section 5(a) to punish inaccurate or misleading privacy policies made by app developers[91] and related service providers.[92]

The US Consumer Financial Protection Bureau (CFPB) has signaled that it might be joining the FTC in this type of enforcement action. In a recent settlement, the CFPB levied a $100,000 civil penalty on an online payments company, arguing that the company deceived

85. *See generally H. Energy and Com. Subcomm. Hearing on Health Care Apps*, 114th Cong. (2016) (opening remarks of Nicolas P. Terry), http://docs.house.gov/meetings/IF/IF17/20160713/105197/HHRG-114-IF17-Wstate-TerryN-20160713.pdf [https://perma.cc/8967-XZDT]; *Disrupter Series*, *supra* note 19.

86. *See App Store Review Guidelines*, APPLE, INC., https://developer.apple.com/app-store/review/guidelines/ [https://perma.cc/6B95-CKWS] (last visited Apr. 4, 2016).

87. *iOS Developer Program License Agreement*, APPLE, INC., at §§ 3.3.8-.10, https://developer.apple.com/programs/terms/ios/standard/ios_program_standard_agreement_20140909.pdf [https://perma.cc/53KZ-D9VV] (last visited Apr. 4, 2016).

88. *See id.* at § 5.1.

89. *Id.* at § 5.1.3.

90. 15 U.S.C. § 45(a)(1) (2012).

91. *See, e.g.*, Press Release, FTC, Fandango, Credit Karma Settle FTC Charges That They Deceived Consumers by Failing to Securely Transmit Sensitive Personal Information (Mar. 28, 2014), https://www.ftc.gov/news-events/press-releases/2014/03/fandango-credit-karma-settle-ftc-charges-they-deceived-consumers [https://perma.cc/5CFC-F6S8].

92. *See, e.g.*, In the Matter of Nomi Technologies, Inc., No. 132-3251 (2015), https://www.ftc.gov/enforcement/cases-proceedings/132-3251/nomi-technologies-inc-matter [https://perma.cc/QP7G-MK4R].

consumers as to the safety and security of its online payments systems.[93]

However, the furthest-reaching legal development in privacy and security has been the FTC's successful positioning of the "unfairness" prong of Section 5(a), arguing that some privacy or security failures are intrinsically "unfair."[94] In *FTC v. Wyndham Worldwide Corp.*,[95] the agency pressed that argument in a case involving multiple security breaches compromising the accounts of 600,000 customers of a hotel chain.[96] The Third Circuit Court of Appeals agreed, noting, "We are . . . not persuaded by Wyndham's arguments that the alleged conduct falls outside the plain meaning of 'unfair.'"[97] Earlier, the FTC had successfully made that argument in its enforcement action against LabMD, Inc., involving the alleged exposure of patient information by a testing laboratory.[98] That case was doubly important because the agency took the position that whether a data custodian was or was not a HIPAA-covered entity did not affect the FTC's jurisdiction, making it harder for developers of mobile medical apps or IoHT devices to exploit any regulatory gaps.[99] Notwithstanding its successes, the FTC continues to press for "federal legislation that would (1) strengthen its existing data security authority and (2) require companies, in appropriate circumstances, to provide notification to consumers when there is a security breach."[100]

At a time of considerable uncertainty as to the data protection laws applying to this emerging class of products, responsible manufacturers will likely pay particular attention to the sub-regulatory statements of relevant agencies. For example, the FTC has published a marketing manual for mobile apps, *Start with Security, A Guide for Business,* which is subtitled *Lessons Learned from FTC Cases.*[101] Similarly, the FDA has published Guidances for device makers dealing

93. In the Matter of Dwolla, Inc., CFPB-0007 (2016), http://files.consumerfinance.gov/f/201603_cfpb_consent-order-dwolla-inc.pdf [https://perma.cc/FS8S-MX9T].

94. *See* FTC v. Wyndam Worldwide Corp., 799 F.3d 236, 258–59 (3d Cir. 2015).

95. *Id.* at 247

96. *Id.* at 242

97. *Id.* at 247.

98. *See* In the Matter of Labmd Inc., No. C-4516, 2016 WL 4128215, at *1 (F.T.C. 2016).

99. *See id.* at *4.

100. *Opportunities and Challenges in Advancing Health Information Technology: Hearing Before the H. Subcomms. on Info. Tech. and Health, Benefits, and Admin. Rules of the H. Comm. on Oversight and Gov't Reform*, 114th Cong. 7 (2016) (statement of Jessica Rich, Director, Bureau of Consumer Protection), https://www.ftc.gov/system/files/documents/public_statements/941063/160322commtestimonyhealthinfo.pdf [https://perma.cc/LF44-KQYS].

101. FED. TRADE COMM'N, START WITH SECURITY, A GUIDE FOR BUSINESS 7 (2015), https://www.ftc.gov/system/files/documents/plain-language/pdf0205-startwithsecurity.pdf [https://perma.cc/2JM8-UMCN].

with issues such as device security design[102] and post-sale surveillance and reporting in the event of security issues.[103]

In its 2015 *Internet of Things* report,[104] the FTC made it clear that security flaws in the IoHT endanger not only data but also physical health. The agency gave the example of a heart pacemaker: "if a pacemaker is not properly secured, the concern is not merely that health information could be compromised, but also that a person wearing it could be seriously harmed."[105] Although the FTC did not recommend immediate IoT-specific legislation to deal with privacy and security risks,[106] the agency noted that IoT issues were further "evidence that Congress should enact general data security legislation."[107]

Finally, the IoHT will face many technology threats that, while related to privacy and security, will not necessarily involve intentional attacks like hacking. For example, hospitals are increasingly concerned about the Federal Communications Commission's (FCC) wireless spectrum rules[108] because of the potential for unlicensed devices to interfere with wireless patient monitoring devices operating on nearby frequencies, such as fetal monitors.[109]

V. PRODUCT QUALITY AND SAFETY

As discussed, HIPAA data protection seldom will apply to data generated or stored on a mobile device, wearable, or IoT node. And outside of HIPAA, there are few well-established norms to suggest the level of data protection expected of mobile health apps or wearables. However, quite different scenarios concerning quality and safety issues

---

102. CTR. FOR DEVICES & RADIOLOGICAL HEALTH, CONTENT OF PREMARKET SUBMISSIONS FOR MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 6–7 (2014), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356190.pdf [https://perma.cc/RPU2-VVUQ].

103. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, POSTMARKET MANAGEMENT OF CYBERSECURITY IN MEDICAL DEVICE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 22 (2016), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf [https://perma.cc/MK9N-TT7J].

104. INTERNET OF THINGS, *supra* note 1.

105. *Id.* at 50.

106. *Id.* at 48.

107. *Id.* at 49.

108. Unlicensed Services in TV and 600 MHz Bands, 30 FCC Rcd. 9551, 9552 (2015), https://www.fcc.gov/document/fcc-adopts-rules-unlicensed-services-tv-and-600-mhz-bands [https://perma.cc/G76M-9AYU].

109. *See, e.g.*, Giuseppe Macri, *Congress Warns FCC of Medical Dangers to Spectrum Sharing*, INSIDE SOURCES (Aug. 3, 2015), http://www.insidesources.com/congress-warns-fcc-of-medical-dangers-to-spectrum-sharing/ [https://perma.cc/LFR2-TJCX].

are posed. The FDA has broad regulatory powers over medical devices, and those powers do not depend on whether the device is intended for use by providers or patients or whether the devices are "traditional" or contemporary wearables and apps. The only legal question is whether the device, wearable, or app is a device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act.[110]

Thus, as developers seek to compete with conventional devices or treatments, they will face existing expectations and norms and a culture of testing and evidentiary standards. Further, FDA regulation of devices does not face such a restrictive hurdle of applicability as the Office for Civil Rights (OCR) faces with HIPAA because the predicate for regulation is the manufacture of a medical device, not whether a particular class of entities is regulated. Notwithstanding, considerable questions remain about the quality and safety of medical apps.[111]

While the general question is whether fitness apps have shown any overall benefits, efficacy is a more narrow and legally focused question. Specifically, the efficacy question asks whether an app or device does what its developer claims. Answering that question requires identifying the burden of substantiation the developer should face. The FTC approach to these questions is reasonably settled. In two cases involving apps that purported to diagnose skin moles, the agency argued that the apps were misleading and their effectiveness was unsubstantiated.[112] Crucially, the FTC required the developers to

---

110. According to section 201(h):

> The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h) (2012); *see also* 21 U.S.C. § 353(a) (2012) ("The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement . . . devices which are . . . not adulterated or misbranded under the provisions of this chapter upon removal from [their] processing, labeling, or repacking establishment.").

111. *See, e.g.*, Karandeep Singh et al., *Developing a Framework for Evaluating the Patient Engagement, Quality, and Safety of Mobile Health Applications*, COMMONWEALTH FUND (Feb. 18, 2016), http://www.commonwealthfund.org/publications/issue-briefs/2016/feb/evaluating-mobile-health-apps [https://perma.cc/6JJZ-NPH4].

112. Order for Permanent Injunction at 2, FTC v. Lasarow, No. 15-cv-1614 (N.D. Ill. 2015), https://www.ftc.gov/enforcement/cases-proceedings/132-3211/health-discovery-corporation-

possess and rely upon "competent and reliable scientific evidence to substantiate that the representation is true."[113] Such substantiating evidence was to be derived from blind "human clinical testing . . . that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true."[114] The agency approach to efficacy was endorsed by the Court of Appeals for the District of Columbia in *POM Wonderful, LLC v. FTC*.[115] Subsequently, the FTC applied the same substantiation standard in *Carrot Neurotechnology*, ordering an app developer to cease making scientifically unsubstantiated claims that its app could improve users' vision or vision test results.[116]

Distinct from the efficacy question is device safety. A substantial number of mobile medical apps, wearables, and IoHT devices would likely satisfy the definition of medical device contained in Section 201(h) of the Federal Food, Drug, and Cosmetic Act.[117] However, in a sub-regulatory Guidance first published in 2013 and renewed in 2015, the FDA indicated its intent to exercise regulatory discretion with regard to most apps and related devices.[118] In this sub-regulatory Guidance, the FDA took a risk-based approach, applying its oversight only to "those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were [not to] function as intended."[119]

---

melapp-matter [https://perma.cc/BX4A-SX8F]; In the Matter of Health Discovery Corp., No. 132-3211, 2015 WL 1744581, at *3 (F.T.C. 2015).

113. *In re Health Discovery Corp.*, 2015 WL 1744581, at *5.

114. *Id.*

115. POM Wonderful, LLC v. FTC, 777 F.3d 478, 483–84 (D.C. Cir. 2015) (involving false claims that POM's pomegranate-based products could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction).

116. In the Matter of Carrot Neurotech., Inc., No. 142-3132, 2016 WL 807980, at *34–35 (F.T.C. 2016) (ordering the company to cease claiming that its product "[i]mproves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100% . . . [and] [r]everses, delays, or corrects aging eye or presbyopia").

117. *See* 21 U.S.C. § 321(h) (2012) (defining "device" to include any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man"); *see also* 21 C.F.R. § 801.4 (2016) (clarifying that "intended use" "refer[s] to the objective intent of the persons legally responsible for the labeling of devices").

118. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 4 (2015) [hereinafter MOBILE MEDICAL APPLICATIONS], http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf [https://perma.cc/KS4E-7UEL].

119. *Id.*

The Guidance posits ten categories of mobile apps.[120] Of those, only seven are patient-, rather than provider-, facing, and of those seven, the agency has elected currently not to regulate devices such as fitness trackers, coaches, or EHR conduits.[121] In fact, only two categories of patient-facing apps will be regulated—those "that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices[,]"[122] or those that "perform[] patient-specific analysis and provid[e] patient-specific diagnosis, or treatment recommendations."[123]

The FDA has posted an additional Guidance dealing with "low risk general wellness products."[124] Essentially, the agency intends to exempt consumer-level devices that generally promote health without referencing specific diseases or conditions and do so without inherent risks or any invasiveness.[125] Products that the FDA will not attempt to regulate include apps that help record caloric intake[126] or products that monitor pulse rate during exercise.[127]

Notwithstanding the FDA's light regulatory touch, app developers and IoHT device manufacturers continue to push for more formal exemption from regulation. For example, the Medical Electronic Data Technology Enhancement for Consumers' Health Act (MEDTECH) would remove from FDA review "software that is intended for the purpose of maintaining or encouraging a healthy lifestyle and [is] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or disorder."[128] Some developers seem to accept when FDA regulation is appropriate. The CEO of a company developing a heart monitor to work with Apple Watch noted: "We are not a fitness

120. *See id.* at 14–18.

121. *See id.*

122. *Id.* at 14. For an example of FDA enforcement in this category, see Letter from James L. Woods, Deputy Dir., Ctr. for Devices and Radiological Health, to Myshkin Ingawale, Co-Founder, Biosense Techs. Private Ltd., (last updated Dec. 12, 2016), http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm [https://perma.cc/B79H-ZATT].

123. MOBILE MEDICAL APPLICATIONS, *supra* note 118, at 15.

124. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2 (2016), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf [https://perma.cc/LXZ7-XRZ5].

125. *See id.*

126. *See id.* at 4–5.

127. *See id.* at 7.

128. Medical Electronic Data Technology Enhancement for Consumers' Health Act, S. 1101, 114th Cong. § 2(o)(1)(B) (2016).

product. This is not a toy. We're talking about people's lives."[129] In contrast, Apple's CEO has stated, "We don't want to put the watch through the [FDA] process . . . because it would hold us back from innovating too much, the cycles are too long."[130]

One final point concerning both quality and safety is the potential for regulation by litigation. For example, class action lawsuits have been filed in California against FitBit, Inc. alleging defects such as overestimating sleep[131] and the inaccurate recording of heartbeats.[132] In a recent article, several common law liability scenarios potentially implicating apps and wearables were identified, including the responsibility of healthcare providers recommending apps and product liability claims against developers.[133]

VI. REVISITING THE IOHT VALUE PROPOSITION

It is too early to make even preliminary judgments as to the contribution of apps and wearables to either individual or population health. Various scenarios are foreseeable. At their leading edge of adoption, there is a suspicion that apps and wearables, while appealing to many, may have limited effectiveness. If so, apps and even some more sophisticated devices may turn out to offer little more than the exercise bracelets that preceded them, useful for those already committed to wellness strategies but expensive toys for others.

At the other extreme, wearables and their attendant software may develop into devices that save lives, make chronic disease states manageable, and provide the richest research data outside the mapped

---

129. Mark Bergen, *Vic Gundotra, Former Google+ Boss, Is Building a Heart Monitor for the Apple Watch*, RECODE (Mar. 16, 2016), http://www.recode.net/2016/3/16/11587010/medical-startup-alivecor-bakes-heart-monitor-into-apple-watch-poaches? [https://perma.cc/Z78H-PG2A].

130. Allister Heath, *Apple's Tim Cook Declares the End of the PC and Hints at New Medical Product*, TELEGRAPH (Nov. 10, 2015), http://www.telegraph.co.uk/technology/2016/01/21/apples-tim-cook-declares-the-end-of-the-pc-and-hints-at-new-medi/?WT.mc_id=tmgoff_pq_tw_20150423 [https://perma.cc/6UY5-T6ES].

131. Complaint at 20, Brickman v. Fitbit, Inc., No. 3:15-cv-2077 (N.D. Cal. 2015), http://ia800308.us.archive.org/34/items/gov.uscourts.cand.287359/gov.uscourts.cand.287359.1.0.pdf [https://perma.cc/L3HL-FCZ3] (alleging that Fitbit devices "consistently overestimated sleep by 67 minutes per night" compared to polysomnography and 43 minutes compared to less-accurate actigraphy).

132. Complaint at 19, McLellan v. Fitbit, Inc., No. 16-cv-36 (N.D. Cal. 2016), http://lchbdocs.com/pdf/Fitbit-class-action-complaint.pdf [https://perma.cc/D6Y2-NSRT] (alleging the company's PurePulse Trackers consistently mis-record heart rates by a very significant margin, particularly during exercise).

133. Nicolas P. Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANNALS HEALTH L. 62 (2016), https://papers.ssrn.com/sol3/papers2.cfm?abstract_id=2725450 [https://perma.cc/7JH4-BNGK]; *see also* Steven Overly, *McDonald's Recalls Activity Trackers Due to Burns, Irritation*, WASH. POST (Aug. 23, 2016), http://wpo.st/dh5T2 [https://perma.cc/W4TK-XUNJ].

genome. For example, some health-related apps appear to provide researchers with richer and more accurate data than typically derived from patient interactions.[134] Also notable is Apple's ResearchKit, "an open source framework . . . that allows researchers and developers to create powerful apps for medical research[.]"[135] It has been particularly successful in enrolling large numbers of patients in studies and producing constant flows of data.[136]

It is difficult to predict which IoHT technologies will be truly disruptive or merely offer healthcare industry incumbents the opportunity to improve existing services. Self-disruption by incumbents is rare, even when they adopt new technologies—what Christensen refers to as "sustaining technologies"—in an attempt to improve existing healthcare models.[137] Here, there is plenty of scope for improvement. For example, we should see seamless access by patients to EHR information, coupled with the ability of patients to upload their personally generated exercise or condition-monitoring data to their provider's EHR, thus adding to the richness of data available.[138] Incumbents are the targets for Apple's "CareKit," introduced in 2016.[139] This open source platform is designed to facilitate the development of apps that, for example, allow patients to track their care plans and action items and record vital signs, emotions and pain, and motion.[140]

Wearables can be leveraged to positively identify patients and seamlessly allow their data to follow them as they proceed through the healthcare system, thus improving care coordination. Take a mundane example: the visit to a hospital or doctor's office and the attendant time spent in a waiting room. IoHT should be able to bring about the "death of queuing,"[141] replacing many of these heretofore seemingly inevitable

---

134. Jenna Wortham, *We're More Honest with Our Phones Than with Our Doctors*, N.Y. TIMES MAG. (Mar. 23, 2016), https://nyti.ms/2jIkbnG [https://perma.cc/9HSY-LA5U].

135. *Introducing ResearchKit*, RESEARCHKIT, http://researchkit.org [https://perma.cc/9XKK-75F8] (last visited Apr. 4, 2016).

136. Christina Farr, *In Its First Year, Has Apple's ResearchKit Revolutionized Medical Research?*, FAST COMPANY (Mar. 22, 2016), http://www.fastcompany.com/3058125/in-its-first-year-has-apples-researchkit-revolutionized-medical-researc [https://perma.cc/8CRZ-6GWM].

137. *See generally* CHRISTENSEN, *supra* note 16.

138. *See, e.g.*, PROTEUS DIGITAL HEALTH, http://www.proteus.com [https://perma.cc/YB3A-3WQU] (last visited Apr. 6, 2016).

139. Press Release, Apple, Inc., Apple Advances Health Apps with CareKit (Mar. 21, 2016), http://www.apple.com/pr/library/2016/03/21Apple-Advances-Health-Apps-with-CareKit.html [https://perma.cc/978W-M7CB].

140. *See generally* Christina Farr, *Apple's First CareKit Apps Are Here*, FAST COMPANY (Apr. 28, 2016), http://www.fastcompany.com/3059372/apples-carekit [https://perma.cc/99SC-UGCP].

141. Nicole Kobie, *Will the Internet of Things Mean the Death of Queuing?*, GUARDIAN (Mar. 31, 2015), https://www.theguardian.com/technology/2015/mar/31/will-the-internet-of-things-mean-the-death-of-queuing?CMP=share_btn_tw [https://perma.cc/CQT9-6X9Z].

delays with virtual visits or by having intelligent agents in pharmacies, provider offices, and patients' medicine cabinets negotiate drug compliance, consumption, refill, and delivery.

True business disruption will occur when traditional providers or their financing mechanisms are replaced, in whole or in part, by new patient-facing technologically mediated models. Indeed, it is likely that there will be a mix of these scenarios, improvement, and disruption. Take, for example, the increasingly powerful artificial intelligence (AI) engines being developed by major technology companies.[142] IBM's "Watson for Oncology" combines its analysis of "the meaning and context of structured and unstructured data in clinical notes and reports" with "clinical expertise, external research, and data," so that "doctors can consider the treatment options provided by Watson when making decisions for individual patients."[143] Watson operates primarily, therefore, as a provider-facing expert system.[144] Compare Google's DeepMind project whose AI is described by a co-founder as follows: "I think the sort of things you'll see this kind of AI do is medical diagnosis of images and then maybe longitudinal tracking of vital signs or quantified self over time, and helping people have healthier lifestyles. I think that'll be quite suitable for reinforcement learning."[145]

The rise of IoT suggests the latter is a more likely result. Of course, at the moment, consumer-facing IoT technologies are rudimentary, relatively underdeveloped, and, in some cases, gimmicky or toy-like. However, they are rapidly iterating.

In the healthcare space, mobile medical apps and wearables likely will continue to develop so as to excel in measuring patient or pre-patient characteristics. However, notwithstanding their skin sensors, their features like accelerometers, location, and other services are not particularly context-sensitive or interactive. It is in this area that the IoHT will add such value.

---

142. *See, e.g.*, Steven Borowiec, *AlphaGo Beats Lee Sedol in Third Consecutive Go Game*, GUARDIAN (Mar. 12, 2016), https://www.theguardian.com/technology/2016/mar/12/alphago-beats-lee-sedol-in-third-consecutive-go-game?CMP=share_btn_tw [https://perma.cc/ADJ8-MUNS]. *See generally* Alistair Dabbs, *AI in Healthcare: Fascinating Tech, but Is It Actually Saving Lives?* ARS TECHNICA (Mar. 24, 2016), http://arstechnica.com/?post_type=post&p=850011 [https://perma.cc/2X88-ZG3C].

143. *IBM Watson for Oncology*, IBM, http://www.ibm.com/watson/health/oncology/ [https://perma.cc/FA45-SRY9] (last visited Apr. 6, 2016).

144. *See* Sam Byford, *DeepMind Founder Demis Hassabis on How AI Will Shape the Future,* VERGE (Mar. 10, 2016), http://www.theverge.com/2016/3/10/11192774/demis-hassabis-interview-alphago-google-deepmind-ai? [https://perma.cc/J9AQ-VFCM] ("I think Watson's very different than what we do, from what I understand of it—it's more like an expert system.").

145. *Id.*

Robust connections between apps and wearables and infrastructure, such as homes, offices, hospitals, and transportation systems, should lead to cost-effective increases in the quality of individual and population health. Apps and wearables will increasingly be aware of their users' environments.[146] Already, automotive navigation systems direct vehicles around accidents or congestion and, increasingly, interact with hybrid engines to promote efficiency along a chosen route.[147] It is not hard to predict that apps and devices will benefit from increased interactions with other devices. Thus, personal devices will receive crowd-sourced[148] or IoT-sourced warnings of pollutant levels unfriendly to their, say, asthmatic hosts and reroute an outdoor activity or automatically increase home or automobile filtration. Similarly, a patient restricted to limited activity because of heart problems would be routed away from a destination where the only elevator was broken, fulfilling the goals of wraparound care without the necessity for formal monitoring by providers.[149] Population health researchers will be able to not only study the activities and diagnostics of a patient or pre-patient but also contextualize that with streams of IoT data regarding environmental and social determinants of health.

Contemporary apps and wearables tend to create data which may or may not translate into usable information. As with other medical advances, such as the increasing availability of genetic data,[150] knowledge does not always facilitate unambiguous action. The question will be whether IoT can "turn data into information, and information into insight"[151] and that knowledge or insight into action.[152] Here, we

---

146. Lonergan, *supra* note 44.

147. *See, e.g.*, Tim Pitt, *BMW 7 Series Prototype Review: 2015 First Drive*, MOTORING RES. (Apr. 18, 2015), https://www.motoringresearch.com/car-reviews/bmw-7-series-prototype-review-2015-first-drive [https://perma.cc/X7G3-4AWJ]; Phil Samson, *GPA Cruise Control Improves Fuel Economy*, TELEGRAPH (Dec. 14, 2011), http://www.telegraph.co.uk/motoring/news/8950891/GPS-cruise-control-improves-fuel-economy.html [https://perma.cc/EW4R-8LEY].

148. *See, e.g.*, Press Release, Novartis, Novartis Pharmaceuticals Collaborates with Qualcomm in Digital Innovation with the Breezhaler(TM) Inhaler Device to Treat COPD (Jan. 5, 2016), https://www.novartis.com/news/media-releases/novartis-pharmaceuticals-collaborates-qualcomm-digital-innovation-breezhalertm [https://perma.cc/EW4R-8LEY].

149. *See generally* David A. Asch et al., *Automated Hovering in Health Care — Watching Over the 5000 Hours*, 367 NEW ENG. J. MED. 1, 1–3, (2012), http://www.nejm.org/doi/full/10.1056/NEJMp1203869#t=article [https://perma.cc/LDS4-ZPAS].

150. *See, e.g.*, Gina Kolata, *When Gene Tests for Breast Cancer Reveal Grim Data but No Guidance*, N.Y. TIMES (Mar. 11, 2016), https://www.nytimes.com/2016/03/12/health/breast-cancer-brca-genetic-testing.html?&_r=0 [https://perma.cc/23YL-FPL5].

151. Carly Fiorina, CEO, HP, Information: The Currency of the Digital Age, Address at Oracle OpenWorld (Dec. 6, 2004), http://www.hp.com/hpinfo/execteam/speeches/fiorina/04openworld.html [https://perma.cc/KK28-UHSU].

152. *See, e.g.*, Eric Horvitz & Tom Mitchell, *From Data to Knowledge to Action: A Global Enabler for the 21st Century*, MICROSOFT (June 27, 2010), https://www.microsoft.com/en-

are likely to see some of the most important contributions of IoT to improved healthcare.

Interactions with IoT devices are not limited to data collection and sharing. Many will transmit the current state or operational status of the device. Thus, an insulin pump would not only transmit an error message in the event of an imminent fault but would notify the patient's nurse to bring a replacement. Similarly, a nurse or social worker could be notified if an elderly patient's apartment heat dropped beneath a certain level or if he had not accessed his pill dispenser for, say, twelve hours.

IoT devices can also be commanded to perform certain actions.[153] For example, a 2016 patent application regarding "Care Event Detection and Alerts" sketched out a scenario whereby a "care event" was detected by a device that then cooperated with other devices in transmitting, monitoring, or further detecting the event.[154] Consider some other, less theoretical examples. If EMS were dispatched to the apartment of the patient who was not drug compliant, the apartment door could be remotely unlocked. More dramatically, the wearable device being worn by a driver that detected signs of an imminent myocardial infarction could not only dispatch emergency services but also order the car to pull over to the side of the road.[155]

VII. CONCLUSION

There were basic healthcare provider-facing medical apps running on the Palm platform as early as 2001,[156] and the Nike+ fitness

---

us/research/wp-content/uploads/2016/02/Evidence_based_healthcare_essay.pdf [https://perma.cc/7HVH-NYEH].

153. *See generally* Andy Daecher & Robert Schmid, *Internet of Things: From Sensing to Doing,* DELOITTE (Feb. 24, 2016), https://dupress.deloitte.com/dup-us-en/focus/tech-trends/2016/internet-of-things-iot-applications-sensing-to-doing.html [https://perma.cc/3KYZ-FXVF].

154. Patent Application 20160071392, United States Patent & Trademark Office (Mar. 10, 2016), http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtml%2FPTO%2Fsearch-adv.html&r=1&p=1&f=G&l=50&d=PG01&S1=(340%2F573.1.CCLS.+AND+20160310.PD.) [https://perma.cc/85E8-88HK].

155. The Ford Motor Company reportedly stopped working on an automobile seat that would detect such medical problems because of the increasing capacities of mobile devices. *See* Matthew Barnes, *Why Did Ford Abandon Its Project Heart Attack Seat*, TECHMALAK (May 5, 2015), http://www.techmalak.com/why-did-ford-abandon-its-project-heart-attack-seat/ [https://perma.cc/K4GA-RHE]. *See generally* Elizabeth Dwoskin & Mike Ramsey, *Car Makers Test Technology to Make You Pay Attention to the Road*, WALL ST. J. (Mar. 11, 2016), http://www.wsj.com/articles/car-tech-that-watches-how-you-drive-1457692201 [https://perma.cc/B3JM-X543].

156. Milt Freudenheim, *Digital Doctoring; The Race Is on to Put a Computer into Every Physician's Hand*, N.Y. TIMES (Jan. 8, 2001) http://www.nytimes.com/2001/01/08/business/digital

tracker that worked with Apple iPods launched in 2006.[157] However, it was not until the announcement of the first generation iPhone in January 2007[158] and, subsequently, the opening of the Apple app store in the middle of 2008[159] that there was an explosion in the availability of pre-patient or patient-facing apps. Later, in 2009, the first Fitbit tracker was launched.[160] Today, consumer-facing, health-inflected information technologies are exhibiting extraordinarily rapid iteration. Yet, these personal health technologies already seem primitive compared to an IoT that will spawn robots[161] and autonomous vehicles.[162]

Although HIT has failed to disrupt, or even transform, conventional healthcare, mobile health apps and wearables offer more promise. They are patient- rather than provider-facing and seldom invoke third-party reimbursement. Although already surprisingly powerful due to their built-in sensors, these technologies will access new levels of contextualization and action when linked to the IoT.

While the resultant IoHT has great promise (some dystopian predictions aside), policymakers and regulators have failed to articulate strong and consistent regulation regarding data protection, efficacy, or safety. Currently, apps, wearables, and IoT hardware and software are

---

-doctoring-the-race-is-on-to-put-a-computer-into-every-physician-s-hand.html?pagewanted=3 [https://perma.cc/TM59-27FV].

157. Press Release, Apple, Inc., Nike and Apple Team Up to Launch Nike+iPod (May 23, 2006), https://www.apple.com/pr/library/2006/05/23Nike-and-Apple-Team-Up-to-Launch-Nike-iPod.html [https://perma.cc/3KNP-6Y9J].

158. Press Release, Apple, Inc., Apple Reinvents the Phone with iPhone (Jan. 9, 2007), http://www.apple.com/pr/library/2007/01/09Apple-Reinvents-the-Phone-with-iPhone.html [https://perma.cc/ZG9T-46VB].

159. Michael Arrington, *iPhone App Store Has Launched (Updated)*, TECHCRUNCH (July 10, 2008), http://techcrunch.com/2008/07/10/app-store-launches-upgrade-itunes-now/ [https://perma.cc/PC49-CNJ3].

160. Tim Stevens, *Fitbit Review*, ENGADGET (Oct. 15, 2009), https://www.engadget.com/2009/10/15/fitbit-review/ [https://perma.cc/5BD8-QMUE].

161. *See generally* Drew Simshaw, Nicolas P. Terry, Dr. Kris Hauser & Dr. M.L. Cummings, *Regulating Healthcare Robots: Maximizing Opportunities While Minimizing Risks*, 22 RICH. J.L. & TECH. 3 (2016). *See, e.g.*, David Meyer, *Meet Zenbo, Asus's $599 Home Robot*, FORTUNE (May 30, 2016), http://fortune.com/2016/05/30/asus-zenbo-robot/ [https://perma.cc/39TS-BR4L].

162. *See, e.g.*, Sarah Buhr, *GM Buys Self-Driving Car Kit Startup Cruise, Plans to Use Tech to Make Driverless Cars*, TECHCRUNCH (Mar. 11, 2016), http://techcrunch.com/2016/03/11/gm-buys-self-driving-tech-startup-cruise-as-part-of-a-plan-to-make-driverless-cars/ [https://perma.cc/35WW-9S9C]; Jonathan M. Gitlin, *10 More OEMs Pledge to Make Auto-Braking Standard in New Cars*, ARS TECHNICA (Mar. 18, 2016), https://arstechnica.com/cars/2016/03/10-more-oems-pledge-to-make-auto-braking-standard-in-new-cars/ [https://perma.cc/XE55-VM6J]; Robert Hackett, *Toyota Just Hired Everyone at This MIT-Born Robotics Startup*, FORTUNE (Mar. 10, 2016), http://fortune.com/2016/03/10/toyota-jaybridge-robotics/ [https://perma.cc/6SGX-ETWK]; Ryan Petersen, *The Driverless Truck Is Coming, and It's Going to Automate Millions of Jobs*, TECHCRUNCH (Apr. 25, 2016), https://techcrunch.com/2016/04/25/the-driverless-truck-is-coming-and-its-going-to-automate-millions-of-jobs/? [https://perma.cc/X3SQ-E9BE].

only lightly regulated. Regarding data protection, the explanation is as simple as it is unfortunate. Outside of the HIPAA "zone," the protection of healthcare information is negligible. The quality and safety situation is more nuanced. The FDA has the power to regulate this area[163] yet has taken something of a hands-off approach, although it seems increasingly concerned about the security of medical devices. Filling in the gaps on, hopefully, only a temporary basis, the FTC is increasingly intervening with regard to apps and devices that are ineffective or threaten privacy. If these technologies are to transform, or even disrupt, our existing healthcare systems, they deserve to be overseen by a consistent and well-thought-out regulation.

163. *See generally* Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175 (2014).